

REMARKS

I. Introduction

The office action (1) acknowledges the request for the interference; (2) requests that the applicants consolidate the references presented in the previous information disclosure statement; (3) objects to the drawings under 37 CFR 1.83(a); (4) rejects claim 55 and objects to the specification under the first paragraph of 35 USC 112; (5) rejects claim 45-54 and 56-64 under 35 USC 103 based upon United States patent No. 4,718,423 to Willis et al. (hereinafter referred to as "the Willis et al. patent") and United States patent No. 4,217,910 to Khalil (hereinafter referred to as "the Khalil patent"); (6) rejects claim 55 under 35 USC 103 based upon the Willis et al. patent, the Khalil patent, and United States patent No. 4,814,586 to Grise (hereinafter referred to as "the Grise patent").

Claims 45-64 remain present for examination.

II. The Request for the Interference

The office action states that:

The examiner acknowledges applicant's request under 37 C.F.R. § 1.607 to provoke an interference with U.S. patent number 5,435,308 to Gallup et al. However, as none of the present claims are allowable, the interference is not being set up.¹

Applicant has asserted that the examiner's reasoning concerning the denial of the request to

¹Office action page 2 lines 1-4.

set up an interference is illogical. It is the examiner's position that applicant has no claims that are presently allowable. Hence, no interference can be set up, by definition. The examiner sees nothing illogical in this.²

In reply, for the reasons presented in the petition to grant the 37 CFR 1.607 request, the applicants assert that the denial of the request for the interference was procedurally incorrect.

United States patent No. 5,450,466 to Kadowaki et al. (hereinafter referred to as "the Kadowaki et al. patent") is submitted herewith in connection with the updated 37 CFR 1.607 request.³

III. The Information Disclosure Statement

The office action states:

The examiner further notes that the old PTO form 892's submitted by applicant and the international search reports have been considered. However, the examiner notes a great deal of overlap in the forms submitted by applicant and requests that applicant review the forms, consolidate the references, eliminating redundancies.⁴

In reply, please find enclosed a consolidated PTO-1449 for the convenience of the examiner.⁵

²Office action page 6 lines 1-6.

³A copy of the Kadowaki et al. patent is attachment 3 to the amendment.

⁴Office action page 2 lines 5-10.

⁵Attachment 1 submitted herewith is the consolidated PTO-1449.

IV. The Objection to the Drawings

The office action states that:

The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the heating filament printed on two sides of a substrate must be shown or the feature canceled from the claim. No new matter should be entered.⁶

In reply, claim 55 has been amended by deleting the recitation that the filament is printed on two opposing sides of the substrate.

V. The Rejection of Claim 55 and the Objection to the Specification Under the First Paragraph of 35 USC 112

The office action states that:

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, fails to provide support for the invention, as now claimed. With respect to claim 55, applicant has recited that the filament is printed on two sides of a substrate. The examiner notes that on pages 19, line 12, applicant recites that the filament is printed int he [sic; in the] middle of a substrate. Therefore, the claim language contradicts the specification and introduces new matter.⁷

In reply, claim 55 has been amended in order to moot the objection and the rejection as discussed in the preceding section.

⁶Office action page 2 lines 11-15.

⁷Office action page 2 line 25 to page 3 line 7.

VI. The Rejection of Claims 45-54 and 56-64 Under 35 USC 103 Based Upon the Willis et al. Patent and the Khalil Patent

The office action states that:

Claims 45-54 and 56-64 are rejected under 35 U.S.C. § 103 as being unpatentable over Willis et al in view of Khalil '910. Willis et al shows all of the features of the claims except that it measures cardiac output using a cold bolus injection. The examiner notes that Willis et al shows the port P' on a "necked down" portion of the catheter. The examiner further notes that the portion 105 of the catheter necks down to portion 101. Hence, portion 101 is the necked down portion. Khalil teaches that cold bolus injections and using external heaters heat the blood are equivalent methods of measuring cardiac output (see background section). Accordingly, it would have been obvious to modify Willis et al to use a heating coil, rather than a cold bolus injection, as it is merely the substitution of one known equivalent measurement technique for another. Claim 46 is rejected for the reasons given above. Claim 47 is rejected in that the necked down portion includes a portion of the catheter that is 14-15 centimeters from the distal end of the device. Claim 48 is rejected in that the heater is a coil wrapped about the necked down portion. Claim 49 is rejected in that there is a thermistor distal to the heater in the combination. Claims 50-52 are rejected in that the coil of the combination has center to center spacings such that adjacent turns do not contact each other, has an outer sheath and the diameter of the coil approximates that of the catheter when wrapped about the catheter. Claim 53 is rejected in that the port P/M' is distal to the interface. Claim 54 is rejected in that the exact distance between the end of the catheter and the heater varies with catheter size and would have been obvious to one skilled in the art. Claims 56-58 and 61-63 are rejected in that the combination shows all of the features of the claims. With respect to claim 57, the examiner notes that Willis has two ports, P/M' and T/F'. With respect to claim 61, the examiner notes that the location of the wiring and optical fibers is not for any particular purpose, nor does it solve any stated problem. Accordingly, it would have been a matter of design choice on how to configure the wiring, as all configurations appear to be equivalent. See In re Kuhle, 526 F.2d 553 (CCPA 1975). Claim 59 and 60 are rejected in that there is a fluid injectate lumen and port P/M' for injecting a fluid into the

blood, that is distal to the interface. Claim 64 is rejected for the reasons given above. In addition, the examiner notes that the location of the ports of the combination will be substantially that recited in the claims.⁸

In reply, the applicants submit (1) that the Willis et al. patent does not show the port P' on the necked down portion of the catheter and (2) the proposed combination is not subject matter defined by the applicants' claims. The Willis et al. patent shows the port P' on the constant radius portion of the catheter, and the constant radius portion of the catheter extends from the manifold connector 105 to the balloon 104.⁹ The manifold connector 105 (1) is not what the Willis et al. patent teaches to be the catheter and (2) does not respond to the "multi-lumen main body portion" recited in the applicants' claims.

In fact, column 6 lines 6-7 in the Willis et al. patent state that the catheter diameter of the catheter is preferably 7.1 French or less and identifies the catheter in Figure 1 as the element 101. Element 101 is the long, constant radius, extending portion of the catheter between the manifold connector 105 and the annular balloon 104. Thus, the catheter 101 has no "necked down portion." The proposed combination's port P' is on the constant radius catheter 101. However, the proposed combination's port P' is not on a necked down portion

⁸Office action page 3 line 27 - page 5 line 13.

⁹Specification column 6 line 9. Incidentally, the applicants note that the term "manifold" is misdescriptive of the connector 105.

of the catheter 101 because the catheter 101 has no necked down portion.

Moreover, the multi-lumen main body portion defined by the applicants' claims does not include the proposed combination's manifold connector 105 connecting the multi-lumen main body portion to the plurality of extension tubes. This is because the applicants' claims explicitly recite the additional element of the "interface" connecting the multi-lumen main body portion and the plurality of the extension tubes. See, e.g., elements (a) - (c) in claim 45. The interface recited in the applicants' claims reads upon the proposed combination's manifold connector for 105. Therefore, the multi-lumen main body portion recited in the applicants claims does not read upon the manifold connector 105. This means that the proposed combination does not have a structure responding to the necked down portion of the multi-lumen main body portion defined by claims 45-60 and 64. Therefore, the assertion in the office action that:

Willis et al[.] shows all of the features of the claims except that it measures cardiac output using a cold bolus injection. The examiner notes that Willis et al[.] shows the port P' on a "necked down" portion of the catheter...¹⁰

is incorrect.

The office action further asserts that:

The examiner further notes that the portion 105 of the catheter necks down to the portion 101.¹¹

¹⁰Office action page 3 lines 29 to page 4 line 1.

¹¹Office action page 4 lines 1-2.

In reply, the applicants respectfully submit that the assertion that the portion 105 of the catheter necks down to the portion 101 is incorrect because the portion 105 is not part of the catheter defined in the Willis et al. patent. Therefore, assuming arguendo that the proposed combination would have been obvious, claims 45-60 and 64 would not have been obvious in view of the Willis et al. patent and the Khalil patent.

The examiner asserts that the location of the wiring and the optical fibers defined by claim 61 is unpatentable over the Willis et al. patent in view of the Khalil patent, stating that:

The location of the wiring and optical fibers is not for any particular purpose, nor does it solve any problems stated.¹²

However, that reasoning does not recognize the very tight spatial limitations in catheters which require the best use of available diametric space. For example, United States patent 5,464,398 to Haindl (hereinafter referred to as "the Haindl patent")¹³ teaches the need for minimizing the cross section of a multi-lumen catheter,¹⁴ and it teaches deforming a separating wall between the lumens.¹⁵ Since the diametrical size of the lumens determines what can be placed in the lumens, it is

¹²Office action page 5 lines 3-5.

¹³A copy of the Haindl patent is submitted herewith as Attachment 2.

¹⁴Column 1 lines 66 to column 2 line 4.

¹⁵Column 2 lines 14-17.

submitted that the placement of wiring and optical fibers in various lumens is not merely a matter of design choice.

Moreover, the Willis et al. patent specifically teaches that its invention is to place both the optical fibers and the wiring in a single lumen, which belies the assertion in the office action.

Defendant claims 62 and 63 depend from claims 61. Therefore, claims 62 and 63 are allowable at least for the reasons that apply to claim 61.

VII. The Rejection of Claim 55 Under 35 USC 103 Based Upon the Willis et al. Patent, the Khalil Patent, and the Grise Patent

The office action states that:

Claim 55 is rejected under 35 U.S.C. § 103 as being unpatentable over Willis et al in view of Khalil as applied to claims 45-54, 56-58, and 61-63 above, and further in view of Grise. Grise teaches that a substrate based heater is an improvement over a single wire of Khalil, in that the cost is much less and the heaters are more flexible in use. Accordingly, it would have been obvious to modify the above combination to use the substrate based heater of Grise, for the reasons given above.¹⁶

Applicant has asserted that Grise et al does not teach an external filament of that [sic; or that] the filament can be incorporated into a cardiac catheter. It is the examiner's position that this argument is irrelevant to prosecution. There is no requirement that there be an explicit suggestion to combine the references. rather, [sic] there need only be some suggestion, obtain [sic; obtained] after viewing the [sic; the] references as a whole. Here, Grise relates to problems in single wire heating filaments. The reference, Khalil, uses a single wire heating filament. Hence, the

¹⁶Office action page 5 lines 14-22.

reference, when viewed as a whole, provide motivation to make the combination.¹⁷

In reply, the applicants submit that the teachings of the Grise patent do not overcome the deficiencies in the proposed combination noted above. Therefore, the modification of the proposed combination of the Willis et al. patent and the Khalil patent based upon the additional teachings in the Grise patent in the manner asserted in the office action does not result in subject matter defined by claim 55. Therefore, claim 55 is also allowable.

Moreover, the applicants dispute the assertion that the Grise patent relates to problems in single wire heating filaments since the Grise patent is directed to a relatively large sheet heater, not a relatively small single wire heater.

VIII. Conclusion

In view of the foregoing comments, it is submitted that all of the claims in this application are allowable. Therefore, the examiner is requested to fill out the initial interference memorandum and forward this application to the Board of Patent Appeals and Interferences for the declaration of the interference.

IX. Addendum

The undersigned is conveniently located within walking distance of the examiner's office. The undersigned hereby requests a personal interview with the examiner for the

¹⁷Office action page 6 lines 9-18.

purposes of overcoming any outstanding issues and expediting
the declaration of the interference.

Respectfully submitted,



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